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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,304	05/11/2001	Shoujun Chen	11355-005001	6057

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EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,304	Applicant(s) CHEN ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 26-28* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 13-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on December 24, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Schutt (US 4248861). Schutt teaches a skin composition comprising Kava Kava and a carrier (Col. 3, lines 33-41, 48-68; Col. 4, lines 1-5; Col. 5, Examples 3 and 4). This composition is applied to the skin to treat burns and can be prepared in any desired manner and in any suitable order or sequence of addition of the various components (Col. 4, lines 31-44). The Kava Kava is present in amounts from 0.5 to 3 parts by weight (Col. 3, lines 33-41). It is the position of the Examiner that Kava Kava contains all the kavalactones claimed in the instant application. Therefore, Schutt anticipates Claim 12.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum (US 5585386). Rosenbaum teaches a topical composition comprising kavain, dihydrokavain, methysticin, dihydromethysticin and a physiologically acceptable carrier (Col. 3, lines 17-67; Col. 4, lines 1-26). The composition is in the form of a ointment or lotion (Col. 4, lines 12-22; Col. 5 & 6, Examples 1, 3 and 4). The kavalactones are

present in the invention from approximately 0.05% to 10% by weight (Col. 3, lines 19-23). Therefore, Rosenbaum anticipates Claim 12.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Kubo et al. (JP 11-189541). Kubo teaches a topical skin application in the form of an ointment or lotion comprising extracts of the Piper Methysticum plant or Kava Kava extracts (See Abstract and Machine Translation enclosed). The extract is present in the composition in amounts from 0.0001 wt% to 20 wt%. Again, it is the position of the Examiner that all the kavalactones are contained in Kava Kava extract. Therefore, Kubo anticipates instant Claim 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt. The teachings of Schutt are discussed above. Schutt does not expressly teach the entire concentration range for the kavalactones.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum. The teachings of Rosenbaum are discussed above. Rosenbaum does not expressly teach the entire concentration range for the kavalactones.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or

temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo. The teachings of Kubo are discussed above. Kubo does not expressly teach the entire concentration range for the kavalactones.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmussen et al. (US 6379696) in view of Elbakyan (WO 00/30578) further in view of Schwabe (US 5296224). Asmussen teaches a transdermal therapeutic system comprising kawain (Col 3- 4, Claim 1).

Asmussen does not expressly teach the patch composition and components of the composition.

Elbakyan teaches a transdermal patch composition comprising an active agent in a polymer matrix (Page 6, lines 10-27), an absorbent layer wherein the active composition is supported and a nonabsorbent backing layer (Page 8, lines 13-30).

Elbakyan does not expressly teach a kavalactone as the active agent

Schwabe teaches that kawain is a kavalactone. Schwabe further teaches other suitable kavalactones such as dihydrokawain, methysticin, dihydromethysticin and yangonin (Col. 1, lines 14-53).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal therapeutic system in the form of a transdermal patch comprising kavalactones. Asmussen teaches kawain in a

transdermal system. Elbakyan teaches the transdermal system can be in the form of a patch. Schwabe teaches the other suitable kavalactones.

One of ordinary skill in the art would have been motivated to do this to provide a slow-release therapeutic composition for topical administration in the treatment of skin conditions, whether it is burns or hypertrophic skin accumulations.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed on December 24, 2002 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a combination of the three recited kavalactones in the recited concentration ranges. Further, applicants argue that the Examiner uses improper hindsight reconstruction.

The Examiner would like to point out that the prior art teaches topical formulations that include Kava Kava extracts. Kava Kava extracts contain kavalactones, more specifically, the three kavalactones recited in the instant claims, among others. The extracts are also incorporated in topical formulations in various amounts. While the prior art does not teach the exact concentration ranges for the three specific kavalactones as recited in the instant claims, the prior art does teach they are known to be in topical formulations. This difference in concentration is a matter of degree and not of kind. Therefore, the Examiner fails to see the criticality in the particular concentration range claimed.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
April 1, 2003

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SUPERVISORY PATENT EXAMINER
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